restricted out (claims 24-50), in one or more continuation and/or divisional applications. Thus, claims 2-13, 17-23, and 51-64 are pending with entry of this amendment.

Information Disclosure Statements.

Applicants note that a supplemental Information Disclosure Statement (IDS) was filed on March 25, 2002 prior to the mailing of the present Office Action dated April 5, 2002. Applicants have not yet received an initialed copy of the Form PTO-1449 submitted with this IDS, showing the Examiner has considered the references cited therein. Applicants briefly discussed this remaining IDS with the Examiner on July 30, 2002 via telephone. Applicants thank the Examiner for his time and willingness to consider the references cited on this IDS mailed on March 25, 2002 prior to issuance of a Notice of Allowance in this application. Copies of all of the references were provided with the IDS filed on March 25, 2002. Applicants respectfully request that the Examiner contact Applicants' attorney (the undersigned) prior to the 6-month deadline of October 5, 2002 in the event this Amendment After Final is not entered and/or the references cited on the IDS filed on March 25, 2002 are not yet considered and made of record.

Applicants note that the Office Action mailed on April 5, 2002 (Paper No. 21) included a copy of a Form PTO-1449 submitted previously by Applicants which showed that the references were considered and initialed by the Examiner on April 2, 2002. These references also appear to have been previously considered and initialed by the Examiner on June 6, 2001, as shown by the Form PTO-1449 that accompanied the Office Action mailed on June 20, 2001 (Paper No. 16).

35 U.S.C. § 103(a).

Claims 1, 14-16, and 65-67 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Stemmer et al. (WO97/20078) in view of Ledley et al. (WO94/25608) and Patten et al. (Current Opinion in Biotechnology (1997) 8:724-733). Office Action, pages 8-9. In an effort to expedite prosecution, claims 1, 14-16, and 65-67 have been cancelled herein without

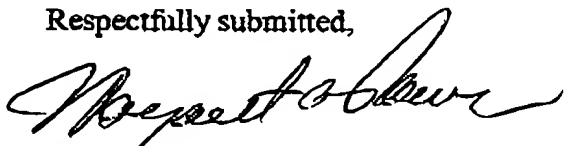
prejudice to subsequent renewal. The cancellation of these claims does not constitute any acquiescence or agreement with any rejection of record. The rejection is thus rendered moot. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. Applicants respectfully request that the Examiner provide an initialed copy of the Form PTO-1449 submitted with the Information Disclosure Statement filed on March 25, 2002, indicating that the references submitted therein have been considered and made of record. Pursuant to the confirmation that these references have been considered, the issuance of a formal Notice of Allowance at an early date is respectfully requested provided the Examiner.

If the Examiner believes a telephone conference would expedite prosecution of this Application, please telephone the undersigned at (650) 298-5809.

Respectfully submitted,



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APPENDIX A

CLEAN SET OF ALL CLAIMS PENDING IN USSN 09/247,886

WITH ENTRY OF THIS AMENDMENT

2. A method for producing and screening a recombinant cell-specific binding moiety for an ability to increase uptake or specificity of a genetic vaccine for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide that encodes a nucleic acid binding domain and at least first and second forms of at least one additional nucleic acid, wherein each of the first and second forms of the additional nucleic acid comprises a polynucleotide that encodes a cell-specific ligand that specifically binds to a protein on the surface of a cell of interest, wherein the first and second forms of each nucleic acid differ from each other in two or more nucleotides, to produce a library of recombinant binding moiety-encoding nucleic acids;

(2) producing a library of vectors from the library of recombinant binding moiety-encoding nucleic acids, wherein each vector comprises: a) a binding site specific for the nucleic acid binding domain and b) a member of the library of recombinant binding moiety-encoding nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the encoded recombinant binding moiety is expressed and recovering the expressed recombinant binding moiety;

(4) binding the expressed recombinant binding moiety to a vector comprising the binding site to form a vector-binding moiety complex;

(5) contacting the vector-binding moiety complex with a target cell of interest; and

(6) determining if one or more target cells contain a vector from the vector-binding moiety complex , and recovering the recombinant cell-specific binding moiety nucleic acid from any such target cells.

3. The method of claim 2, wherein the method further comprises:

(7) recombining at least one recombinant binding moiety-encoding nucleic acid of (6) with a further form of the polynucleotide that encodes a nucleic acid binding domain and/or a further form of the polynucleotide that encodes a cell-specific ligand, which are the same or different from the first and second forms, to produce a further library of recombinant binding moiety-encoding nucleic acids;

(8) producing a further library of vectors from the further library of recombinant binding moiety-encoding nucleic acids, wherein each vector in the further library of vectors comprises: a) a binding site specific for the nucleic acid binding domain and b) a member of the further library of recombinant binding moiety-encoding nucleic acids;

(9) introducing one or more members of the further library of vectors into one or more host cells, wherein the encoded recombinant binding moiety is expressed and recovering the expressed recombinant binding moiety;

(10) binding the expressed recombinant binding moiety of (9) to a vector comprising the binding site to form a vector-binding moiety complex;

(11) contacting the vector-binding moiety complex of (10) with a target cell of interest and determining if one or more target cells contain a vector from the vector-binding moiety complex of (10);

(12) recovering the recombinant binding moiety-encoding nucleic acid from any such target cells of (11); and

(13) repeating (7) through (12) to screen for a cell-specific binding moiety useful for increasing uptake or specificity of a genetic vaccine vector for a target cell.

4. The method of claim 2, wherein the method comprises screening for one or more cell-specific binding moieties that increase uptake of a genetic vaccine vector by the target cells.

5. The method of claim 2, wherein the nucleic acid binding domain is a DNA binding domain derived from a protein selected from the group consisting of a transcriptional regulator, a polypeptide involved in DNA replication or recombination, a repressor, a histone, a protamine, an E. coli CAP protein, myc, a protein having a leucine zipper, a protein having a

DNA binding basic domain, a protein having a POU domain, a protein having a zinc finger, and a protein having a Cys3His (SEQ ID NO:6) box.

6. The method of claim 2, wherein the nucleic acid binding domain is an RNA binding domain derived from a protein selected from the group consisting of HIV *tat* and HIV *rev*.

7. The method of claim 2, wherein the target cell of interest is selected from the group consisting of muscle cells, monocytes, dendritic cells, B cells, T cells, Langerhans cells, keratinocytes, M-cells, liver cells and epithelial cells.

8. The method of claim 7, wherein the target cell of interest is a professional antigen presenting cell.

9. The method of claim 8, wherein the antigen presenting cell is a dendritic cell, a monocyte/macrophage, a B cell, or a Langerhans cell.

10. The method of claim 8, wherein the cell-specific ligand comprises a polypeptide derived from a protein selected from the group consisting of CD2, CD28, CTLA-4, CD40 ligand, fibrinogen, ICAM-1, Fc portion of immunoglobulin G, and a bacterial enterotoxin, or a subunit thereof.

11. The method of claim 2, wherein the target cell of interest is a human cell.

12. The method of claim 2, wherein target cells that contain the vector are identified by selecting for expression of a selectable marker contained in the vector.

13. The method of claim 2, wherein each recombinant binding moiety-encoding nucleic acid comprises a genetic vaccine vector.

17. A composition for eliciting an immune response that comprises:

a) a recombinant binding moiety that comprises a nucleic acid binding domain and a cell-specific ligand, and

b) a polynucleotide sequence that is capable of expressing an antigen and that comprises a binding site, wherein the nucleic acid binding domain is capable of specifically binding to the binding site.

18. A method for producing and screening a recombinant cell-specific binding moiety for an ability to increase uptake, efficacy, or specificity of a vaccine or antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid, wherein each of the first and second forms of the nucleic acid comprises a polynucleotide which encodes a binding moiety of an enterotoxin, wherein the first and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) producing a library of vectors from the library of recombinant nucleic acids, wherein each vector comprises a member of the library of recombinant nucleic acids;

(3) introducing one or more members of the library of vectors into one or more host cells, wherein the member of the library of recombinant nucleic acids is expressed to form a recombinant cell-specific binding moiety polypeptide and recovering the recombinant cell-specific binding moiety polypeptide;

(4) contacting the recombinant cell-specific binding moiety polypeptide with a cell surface receptor of a target cell; and

(5) determining if the recombinant cell-specific binding moiety polypeptide exhibits enhanced ability to bind to the target cell.

19. The method of claim 18, wherein the cell surface receptor is present on the surface of a target cell during said contacting.

20. The method of claim 18, wherein the cell surface receptor is G_{M1}.

21. The method of claim 18, wherein the host cell is a *V. cholerae* cell which is incapable of expressing CT-A.

22. A method for producing a composition for eliciting an immune response, the method comprising coating a polynucleotide that is capable of expressing an antigen with a recombinant cell-specific binding moiety produced by the method of claim 18.

23. The method of claim 18, wherein the recombinant cell-specific binding moiety polypeptide is expressed as a fusion protein on the surface of a replicable genetic package.

51. A method for producing and screening a recombinant cell-specific binding moiety polypeptide for an ability to increase uptake, efficacy, or specificity of a vaccine antigen for a target cell, the method comprising:

(1) recombining at least first and second forms of at least one nucleic acid that comprises a polynucleotide which encodes a cell-specific binding moiety, wherein the first

and second forms differ from each other in two or more nucleotides, to produce a library of recombinant nucleic acids;

(2) introducing one or more members of a library of vectors, each of which comprises a member of the library of recombinant nucleic acids, into one or more host cells, wherein the member of the library of recombinant nucleic acids is expressed to form a recombinant cell-specific binding moiety polypeptide;

(3) contacting the recombinant cell-specific binding moiety polypeptide with a cell surface receptor of a target cell;

(4) determining if the recombinant cell-specific binding moiety polypeptide exhibits enhanced ability to bind to the target cell; and

(5) fusing or linking the recombinant cell-specific binding moiety polypeptide to the vaccine antigen or coating the vaccine antigen with the recombinant cell-specific binding moiety polypeptide.

52. The method of claim 51, wherein each recombinant cell-specific binding moiety polypeptide is expressed as a fusion protein on the surface of a replicable genetic package.

53. The method of claim 51, wherein the recombinant cell-specific binding moiety polypeptide is fused or linked to the vaccine antigen.

54. The method of claim 51, wherein the target cell is selected from the group consisting of muscle cells, monocytes, dendritic cells, B cells, T cells, Langerhans cells, keratinocytes, M-cells, liver cells and epithelial cells.

55. The method of claim 51, wherein the cell surface receptor is present on the surface of a target cell during said contacting.

56. The method of claim 51, wherein the cell-specific binding moiety comprises a polypeptide derived from a protein selected from the group consisting of selected from the group consisting of CD2, CD28, CTLA-4, CD40, and ligands thereof; fibrinogen; factor X; ICAM-1; β-glycan; Fc portion of immunoglobulin G; and a bacterial enterotoxin, or a subunit thereof.

57. A method for producing a composition for eliciting an immune response, said method comprising coating an antigen with a recombinant cell-specific binding moiety polypeptide produced by the method of claim 51.

58. A composition for eliciting an immune response comprising an antigen and a recombinant cell-specific binding moiety polypeptide, wherein the composition is produced by the method of claim 51, wherein:

(i) the antigen comprises a polypeptide antigen;

(ii) the cell-specific binding moiety polypeptide exhibits enhanced ability to bind to the target cell; and

(iii) the polypeptide antigen and the recombinant cell-specific binding moiety polypeptide are derived from different polypeptides.

59. The method of claim 2, wherein the binding site of each vector is derived from a binding site present in at least one form of at least one nucleic acid of (1).

60. The method of claim 2, wherein the binding site is joined to the member of the library of recombinant binding moiety-encoding nucleic acids after said recombining.

61. The method of claim 2, wherein the vector-binding moiety complex forms inside the host cell and, prior to the contacting of (5), the host cell is lysed under conditions that do not disrupt the vector-binding moiety complex.

62. The method of claim 3, wherein the vector-binding moiety complex of (10) forms inside the host cell and, prior to the contacting of (11), the host cell is lysed under conditions that do not disrupt the vector-binding moiety complex.

63. The method of claim 2, wherein the cell-specific ligand comprises a polypeptide derived from a protein selected from the group consisting of CD2, CD28, CTLA-4, CD40, and ligands therefor; fibrinogen; factor X; ICAM-1; β-glycan; Fc portion of immunoglobulin G; and a bacterial enterotoxin, or a subunit thereof.

64. The method of claim 51, wherein the vaccine antigen is coated with the recombinant cell-specific binding moiety polypeptide.